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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/706,892      | 11/13/2003  | Pci-Yong Shi         | 454311-2231.1       | 1951             |

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EXAMINER

SALVOZA, M FRANCO G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/706,892

Applicant(s)

SHI ET AL.

Examiner

M. Franco Salvoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-94 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

✓

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, 28-32, drawn to a reverse genetics system and a recombinant plasmid comprising it, classified in class 536, subclass 23.1.
- II. Claim 18, drawn to a method for preparing a fully-infectious RNA transcript, classified in class 536, subclass 23.1.
- III. Claim 19, 22-27, drawn to a method for preparing a cell line, classified in class 435, subclass 325.
- IV. Claims 20, 21, drawn to a cell line stably replicating the reverse genetics system, classified in class 435, subclass 325.
- V. Claim 33, drawn to a method of identifying potential antiviral chemotherapeutics, classified in class 424, subclass 184.1.
- VI. Claims 34-38, drawn to a method of collecting and transmitting a dataset, classified in class 710, subclass 717.
- VII. Claim 39, drawn to a pharmaceutical composition comprising the antiviral chemotherapeutic, classified class 424, subclass 184.1.
- VIII. Claim 40, drawn to a method for administering the pharmaceutical composition, classified in class 424, subclass 184.1.
- IX. Claim 41, 42, drawn to a method for generating a potential attenuated WNV vaccine, classified in class 424, subclass 184.1.

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- X. Claim 43, drawn to method of generating a live attenuated WNV lineage I virus vaccine, classified in class 424, subclass 184.1.
- XI. Claim 44, drawn to method of treating a flaviviral infection, classified in class 424, subclass 184.1.
- XII. Claims 45-69, drawn to a DNA molecule, classified in class 536, subclass 23.1.
- XIII. Claims 70-79, 89, drawn to a method for screening a plurality of compounds, classified in class 436, subclass 501.
- XIV. Claim 70, 91, 92 drawn to a composition comprising the flavivirus inhibitor, classified in class 424, subclass 184.1.
- XV. Claim 80-88, 90, drawn to a high throughput assay for screening, classified in class 436, subclass 501.
- XVI. Claims 93, 94, drawn to a cell line comprising the DNA molecule, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Invention I and Inventions II, IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case infectious RNA transcripts and viral vaccines can be prepared using other materially different products than a reverse genetics system and other materially different method steps than the ones claimed. In addition, a reverse genetics

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system can be used to code for other materially different products other than RNA transcripts such as specific peptide sequences or proteins.

Inventions I, IV, VII, XII, XIV, XV, and XVI are separate products having distinct functions, distinct structures, and distinct physical, chemical and functional properties requiring separate searches of the prior art.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case cell lines can be used for other materially different purposes other than replicating the reverse genetics system such as generating proteins or specific enzymes in large quantities.

Inventions VII and XIV and Inventions V, VI, VIII, XI and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case flaviviral infections and their symptoms can be treated using materially different products other than a compound comprising the inhibitor.

Invention V, VI, VIII, IX, XI and XIII all represent different methods. Each is distinct from the other. The methods variously utilize different reagents, have different method steps, and/or achieve different goals. References that teach one method would not necessary disclose the other methods.

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Invention XIII and Inventions XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case high throughput assays can be used in a wide variety of materially different processes other than screening for flavivirus inhibitors. In addition, a plurality of compounds can be screened using materially different products such as plaque reduction neutralization tests and ELISA tests.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XVI, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of

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the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116. Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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